

Remarks

Claims 25-70 are pending in the instant application. Claims 25-50 have been found allowable.

The Examiner has noted that the rejection under 35 U.S.C. § 101 has been withdrawn in view of Applicants' arguments and the teaching in the specification that the claimed protein functions solely in the production of IL-10. *See* Paper No. 20040113, page 2, lines 5-7. Applicants respectfully take exception with the term "solely" as used by the Examiner. Applicants have never asserted that the claimed protein (known in the art as DAP12) functions "solely" in the production of IL-10. Applicants assert that the claimed invention has other functions besides inducing IL-10 production, *e.g.*, as a diagnostic marker or as an immunogen, as disclosed in the specification at page 59, lines 10-12 and page 29, lines 25-26. The claims were amended to capture protein variants having the same biological activity as the claimed invention. In light of the above statements, Applicants respectfully request clarification regarding the term "solely" as used by the Examiner.

I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 51-70 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which Applicants regards as the invention. Specifically, the Examiner alleges:

Claims 51-70 are indefinite because it is not clear as to whether the claim language is intended to be "open" (i.e., consisting of) or "closed" (i.e., comprising) claim language. Claims 51-70 recite, "an isolated protein *consisting of* a fragment of ... SEQ ID NO:164, wherein said fragment is *at least* 30 contiguous amino acid residues in length". Therefore, the claim recites, "closed," claim language (i.e., consisting of), followed by "open" claim language (i.e., at least, which is equivalent to "comprising"). That is, the recitation of "at least" could comprise a fragment of SEQ ID NO:164 and a plurality of possible contiguous amino acid residues flanking said fragment of SEQ ID NO:164.

See Paper No. 20040113, page 2, line 20 to page 3, line 4.

Applicants respectfully disagree and traverse. Applicants believe that the Examiner is misinterpreting the claims as written. Applicants have claimed a protein

“consisting of a fragment of amino acid residues 27 to 111 of SEQ ID NO:164, wherein said fragment is at least 30 contiguous amino acid residues in length.” The rejected claims recite “closed” claim language, *i.e.*, in claim 51, the fragment must be a sequence within residues 27 to 111 of SEQ ID NO:164 and further must be at least 30 contiguous amino acids residues in length. Examples of the proteins that are covered by claim 51 include amino acids residues 27 to 56 of SEQ ID NO:164, amino acids residues 28 to 57 of SEQ ID NO:164, *etc.* No flanking sequences are encompassed in these claims as the claims recite “closed,” *i.e.*, consisting of, claim language.

In view of the above, Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph, has been obviated. Accordingly, Applicants respectfully request that the rejection of claims 51-70 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of claims 51-70 under 35 U.S.C. § 112, first paragraph. The Examiner alleges that said claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, primarily for the same reason articulated in the rejection discussed above.

Applicants disagree and traverse. Applicants reiterate that the test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Federal Circuit recently re-emphasized the well-settled principle of law that “[t]he written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,’” *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), hereinafter referred to as “*Unocal*.” While the applicant must “blaze marks on trees,” rather than “simply [provide] the public with a forest of trees,” an Applicant is not required to

explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. As the court noted, “the issue is whether one of skill in the art could derive the claimed ranges from the patent’s disclosure.” *Unocal*, 208 F.3d at 1001 (emphasis added).

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application. Applicants claim a protein “consisting of a fragment of amino acid residues 27 to 111 of SEQ ID NO:164, wherein said fragment is at least 30 contiguous amino acid residues in length.” Applicants assert that this is not “open” claim language, but rather “closed” claim language on account of the intervening phrase for the reasons stated above.

The Examiner suggests including functional language in claims 51-70 to overcome the 35 U.S.C. § 112, first paragraph rejection. However, the specification describes and teaches uses of the claimed fragments that do not require a retention of biological activity, for example, as an immunogen to produce antibodies against DAP12 polypeptides. *See* pages 653-658 of the specification. Accordingly, the skilled artisan would be able to readily envision and identify each and every sequence consisting of a fragment of at least 30 or 50 contiguous amino acids residues of SEQ ID NO:164 or to the polypeptide encoded by the HOSFD58 cDNA.

Thus, armed with what was known in the art at the time the instant application was filed, one of skill in the art could readily envision, make and screen the claimed DAP12 protein fragments. The specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. In view of the arguments above, Applicants submit that claims 51-70 fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner’s rejection of claims 51-70 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.


Conclusion

Applicants respectfully request the amendments and remarks of the present response be entered and made of record in the present application. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the allowance of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: February 27, 2004


Janet M. Martineau (Reg. No. 46,903)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
(301) 315-2723 (phone)

KKH/JMM/JL/vr